

REMARKS

Reconsideration is respectfully requested.

A substitute specification has been included with this reply.

Claims 1-2, 6-7, 16, 18, 21, and 30 have been amended. Claims 3-5, 8-9, 17, 22-29 and 32 are Canceled. Claims 10-15, 19-20, and 27-29 are reiterated. Claims 1-2, 6-7, 10-16, and 18-21, and 30-31 are pending.

The amendments to the claims do not represent new matter. Support for the claims may be found throughout the specification, see for example, page 5, lines 5-17.

Supplemental Information Disclosure Statement

A Supplemental Information Disclosure Statement has been filed with this response. As requested by the Examiner, the Supplemental Information Disclosure Statement includes a reference indicative of the state of the art with respect to purifyably-labeled ribonucleotides (See, Leadon, Nucleic Acids Res. 1986):

Telephonic Interview

Applicants thank Examiner Sisson for the very helpful interview of May 24, 2004. The pending rejections were discussed and the claims have been amended in light of those discussions.

Duplicate Claim

The Examiner has indicated that claim 5 is a substantial duplicate of claim 3. Claim 5 has been canceled.

Specification

The Examiner has noted that the patent application includes a number of trademarked products. Applicants have amended the application by submission of a substitute specification

given the extensive nature of the amendments. Note: references to Beckman, Falcon, Eppendorf, Univar, Ambion, and Sigma have not been amended as they are used as the names of the companies (i.e., the name the company the product was bought from) and not trademarks (i.e., the name of the product bought):

35 U.S.C §112, first paragraph, written description

The Examiner has rejected claims 1-3, 5-7, and 10-32 for failing to comply with the written description requirement. The Examiner has argues that the specification does not reasonably convey to one of ordinary skill in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 1-20, 30 and 31

The Examiner has asserted that determination of the “rate of transcription” and “a change in activity of one or more transcriptional units at different stages of cellular development” are not adequately disclosed.

The applicants respectfully disagree. The specification sets forth the quantification of the several nascent RNA transcripts in Example 19 in the specification which spans 32-70 and in Figures 1-6. As one of skill in the art is well aware, the quantity of nascent transcript is directly related to the rate of transcription of that gene. Thus, no further calculation is needed.

However, in order to facilitate prosecution in this case applicants have amended the pending claims, without prejudice or disclaimer, to recite “quantification of nascent RNA transcripts.” With the amendment, the claims no longer include “determination of the rate of transcription” or “detecting a change in the activity of a transcriptional unit.” As indicated above, the specification clearly discloses quantification of nascent RNA transcripts. One of skill in the art may readily apply the claimed methods to the entire range of organisms. The examiner has suggested that the specification would need to disclose primers for every gene of every organism. However, Applicants are not required to disclose what is well known or conventional in detail. See *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F. 2d at 1384, 231 USPQ at 94. Design of primers for

detection nascent transcripts of such genes by PCR are well known techniques in the art and have been practiced since PCR was developed well over a decade prior to the filing of this application. Applicants therefore respectfully request that the Examiner withdraw the rejection.

Claims 22-29 and 32

The Examiner has rejected claims 22-27 as allegedly failing to comply with the written description requirement. The Examiner admits that the specification supports a variety of possible configurations, but alleges that the Specification “fails to provide an adequate written description of the kits such that one would be able to recognize one assortment of products and be able to readily determine if one assortment or kit is, or is not, encompassed by the claims.”

Applicants respectfully disagree. However, in order to facilitate prosecution in this case applicants have canceled the pending claims, without prejudice or disclaimer. Applicants reserve the right to pursue such claims in later continuation applications.

35 U.S.C §112, first paragraph, best mode

The Examiner has rejected claims 1-3, 5-8 and 10-32 for failing to disclose the best mode. The Examiner has cited as evidence of concealment of the best mode that the specification does not adequately set forth determination of how the rate of transcription is calculated.

The applicants respectfully disagree. It is well established that an inventor does not necessarily even have a best mode. Thus, lack of disclose of a mode cannot be evidence that the inventor has concealed such mode. Furthermore, the specification sets forth the quantification of the several nascent RNA transcripts in Example 19 in the specification which spans 32-70 and in Figures 1-6. As one of skill in the art is well aware, the quantity of nascent transcript is directly related to the rate of transcription of that gene. Thus, no further calculation is needed.

However, in order to facilitate prosecution in this case applicants have amended the pending claims, without prejudice or disclaimer, to recite “quantification of nascent RNA transcripts.” With the amendment, the claims no longer include “determination of the rate of transcription” or “detecting a change in the activity of a transcriptional unit.”

Applicants respectfully request that the Examiner withdraw the best mode rejection.

35 U.S.C. §112, second paragraph

Claims 1-3, 5-7, 10-21, 30 and 31

The Examiner has rejected claims 1-3, 5-7, 10-21, 30 and 31 as being indefinite for failing to particularly point out or distinctly claim the invention. The Examiner argues that the claims omit essential steps amounting to a gap between claims. The Examiner argues that the omitted steps are steps that result in the actual determination of the rate of transcription of a transcriptional unit.

Applicants respectfully disagree and assert that they have not omitted any steps. The step of determining the rate of transcription is accomplished by quantification of the nascent transcripts as discussed above. However, in order to facilitate prosecution in this case applicants have amended the pending claims, without prejudice or disclaimer, to recite “quantification of nascent RNA transcripts.” With the amendment, the claims no longer include “determination of the rate of transcription” or “detecting a change in the activity of a transcriptional unit.”

This ground for rejection is therefore moot. Applicants respectfully request that it be withdrawn.

Claims 1, 6, 8, 22, and 23

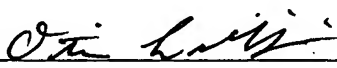
The Examiner has rejected claims 1, 6, 8, 22, and 23 as indefinite for using the term “real time PCR.” The Examiner argues that the term “real time” is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree or scope of the claim.

Applicants respectfully traverse this rejection. The plain meaning of RT-PCR, as discussed above, is readily known to those of ordinary skill in the art. However, in order to facilitate prosecution in this case applicants have amended the pending claims, without prejudice or disclaimer, to recite "quantitatively determining the level of the nascent RNA transcripts." With the amendment, the claims no longer include "real time PCR." One of skill in the art is well aware of numerous methods of quantifying nascent RNA transcripts.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. According, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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